

Application No. 10/807,897 - - - - 2

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**Amendments to the Claims**

This listing of claims will replace all prior versions, and listings, of claims in the application:

**Listing of Claims:**

Claim 1 (original): A DNA vaccine suitable for eliciting an immune response against cancer cells comprising a DNA construct operably encoding at least one cancer-associated Inhibitor of Apoptosis-family protein (IAP-family protein) and at least one immunoactive gene product in a pharmaceutically acceptable carrier.

Claim 2 (currently amended): The DNA vaccine of claim 1 wherein the cancer-associated IAP-family protein is selected from the group consisting of a survivin protein and a livin protein.

Claim 3 (withdrawn): The DNA vaccine of claim 1 wherein the DNA operably encodes a survivin protein selected from the group consisting of (a) wild-type human survivin having the amino acid residue sequence of SEQ ID NO: 2, (b) an immunogenic homolog of wild-type human survivin having an amino acid residue sequence at least 80% identical to SEQ ID NO: 2, (c) a splice variant of human survivin having the amino acid residue sequence of SEQ ID NO: 23, (d) a splice variant of human survivin having the amino acid residue sequence of SEQ ID NO: 24, and (e) a fragment of a survivin protein that binds to a MHC class I molecule and is recognized by cytotoxic T cells.

Claim 4 (withdrawn): The DNA vaccine of claim 1 wherein the DNA construct operably encodes wild-type human survivin having the an amino acid residue sequence of SEQ ID NO: 2.

Application No. 10/807,897 - - - - 3

**Claim 5 (withdrawn):** The DNA vaccine of claim 1 wherein the DNA construct operably encodes human survivin splice variant having the an amino acid residue sequence of SEQ ID NO: 23.

**Claim 6 (withdrawn):** The DNA vaccine of claim 1 whercin the DNA construct operably encodes human survivin splice variant having the an amino acid residue sequence of SEQ ID NO: 24.

**Claim 7 (withdrawn):** The DNA vaccine of claim 1 wherein the DNA construct operably encodes an immunogenic homolog of wild-type human survivin having an amino acid residue sequence at least 80% identical to SEQ ID NO: 2.

**Claim 8 (withdrawn):** The DNA vaccine of claim 1 wherein the DNA construct operably encodes an immunogenic homolog of wild-type human survivin having an amino acid residue sequence at least 90% identical to SEQ ID NO: 2.

**Claim 9 (withdrawn):** The DNA vaccine of claim 1 wherein the DNA construct operably encodes an immunogenic homolog of wild-type human survivin having an amino acid residue sequence at least 95% identical to SEQ ID NO: 2.

**Claims 10-15 (canceled).**

**Claim 16 (withdrawn):** The DNA vaccine of claim 1 wherein the immunoactive gene product operably encoded by the DNA construct is a cytokine or a ligand for a natural killer cell surface receptor.

**Claim 17 (withdrawn):** The DNA vaccine of claim 16 wherein the cytokine is selected from the group consisting of a chemokine, a hematopoietin, an interferon, a natural killer cell stimulatory factor, and a cytokine production-inducing factor.

**Claim 18 (withdrawn):** The DNA vaccine of claim 17 wherein the cytokine is human CCL21.

**Claim 19 (withdrawn):** The DNA vaccine of claim 16 wherein the ligand for a natural killer cell surface receptor operably encoded by the DNA construct is a stress-

Application No. 10/807,897 - - - - 4

inducible protein selected from the group consisting of human MICA, human MICB, human ULBP1, human ULBP2, and human ULBP3.

Claim 20 (withdrawn): The DNA vaccine of claim 1 wherein the DNA construct is operably incorporated in a plasmid vector.

Claim 21 (withdrawn): The DNA vaccine of claim 1 wherein the DNA construct is operably incorporated in an attenuated bacterial vector.

Claim 22 (withdrawn): The DNA vaccine of claim 21 wherein the attenuated bacterial vector is selected from the group consisting of attenuated *Salmonella typhimurium*, *Salmonella typhi*, *Shigella* species, *Bacillus* species, *Lactobacillus* species, *BCG*, *Escherichia coli*, *Vibrio cholerae*, *Campylobacter* species, and *Listeria* species.

Claim 23 (withdrawn): The DNA vaccine of claim 21 wherein the attenuated bacterial vector is an attenuated *Salmonella typhimurium*.

Claim 24 (withdrawn): The DNA vaccine of claim 23 wherein the attenuated *Salmonella typhimurium* is an *AroA*  $\sim$  strain of *Salmonella typhimurium*.

Claim 25 (withdrawn): The DNA vaccine of claim 23 wherein the attenuated *Salmonella typhimurium* is an *AroA*  $\sim$ , *dam*  $\sim$  strain of *Salmonella typhimurium*.

Claim 26 (original): The DNA vaccine of claim 1 wherein the DNA construct operably encoding the cancer-associated IAP-family protein comprises a polynucleotide sequence selected from the group consisting of SEQ ID NO: 1, SEQ ID NO: 3, SEQ ID NO: 26 and SEQ ID NO: 28.

Claim 27 (original): The DNA vaccine of claim 26 wherein the DNA construct is operably incorporated in an attenuated *Salmonella typhimurium* vector.

Claim 28 (original): The DNA vaccine of claim 1 wherein the DNA construct operably encoding the immunoreactive gene product comprises a polynucleotide sequence selected from the group consisting of SEQ ID NO: 5, SEQ ID NO: 7, SEQ ID NO: 11, SEQ ID NO: 13, SEQ ID NO: 15, SEQ ID NO: 17, SEQ ID NO: 19, and SEQ ID NO: 21.

Application No. 10/807,897 - - - - 5

Claim 29 (original): The DNA vaccine of claim 28 wherein the DNA construct is operably incorporated in an attenuated *Salmonella typhimurium* vector.

Claim 30 (withdrawn): A method of inhibiting tumor growth in a mammal comprising the step of administering to the mammal an effective immunological response eliciting amount of a DNA vaccine comprising a DNA construct operably encoding a cancer-associated IAP-family protein and an immunoactive gene product in a pharmaceutically acceptable carrier, whereby said mammal exhibits an immune response elicited by vaccine and specific to tumor cells.

Claim 31 (withdrawn): The method of claim 30 wherein the cancer-associated IAP-family protein encoded by the DNA construct is selected from the group consisting of a survivin protein and a livin protein.

Claim 32 (withdrawn): The method of claim 30 wherein the immunoactive gene product encoded by the DNA construct is a cytokine or a ligand for a natural killer cell surface receptor.

Claim 33 (withdrawn): The method of claim 30 wherein the mammal is a human.

Claim 34 (withdrawn): The method of claim 30 wherein the DNA construct is operably incorporated in an attenuated bacterial vector.

Claim 35 (withdrawn): The method of claim 34 wherein the attenuated bacterial vector is selected from the group consisting of attenuated *Salmonella typhimurium*, *Salmonella typhi*, *Shigella* species, *Bacillus* species, *Lactobacillus* species, *BCG*, *Escherichia coli*, *Vibrio cholerae*, *Campylobacter* species, and *Listeria* species.

Claim 36 (withdrawn): The method of claim 34 wherein the attenuated bacterial vector is an attenuated *Salmonella typhimurium*.

Claim 37 (withdrawn): The method of claim 36 wherein the attenuated *Salmonella typhimurium* is an *AroA* - strain of *Salmonella typhimurium*.

Application No. 10/807,897 - - - - 6

Claim 38 (withdrawn): The DNA vaccine of claim 36 wherein the attenuated *Salmonella typhimurium* is an *AroA* -, *dam* - strain of *Salmonella typhimurium*.

Claim 39 (withdrawn): An article of manufacture comprising a vaccine of claim 1 packaged in a hermetically sealed, sterile container, the container having a label affixed thereto, the label bearing printed material identifying the vaccine and providing information useful to an individual administering the vaccine to a patient.

Claim 40 (withdrawn): An isolated plasmid vector comprising a DNA construct operably encoding a cancer-associated IAP-family protein and an immunoactive gene product.

Claim 41 (withdrawn): A transformed host cell transfected with a vector comprising a DNA construct operably encoding a cancer-associated IAP-family protein and an immunoactive gene product.

Claim 42 (withdrawn): A method of vaccinating a mammal against cancer, the method comprising the step of administering to the mammal an effective immunological response eliciting amount of a DNA vaccine comprising a DNA construct operably encoding a cancer-associated IAP-family protein and an immunoactive gene product in a pharmaceutically acceptable carrier, whereby said mammal exhibits an immune response elicited by vaccine and specific to tumor cells.

Claim 43 (withdrawn): The method of claim 42 wherein the cancer-associated IAP-family protein encoded by the DNA construct is selected from the group consisting of a survivin protein and a livin protein.

Claim 44 (withdrawn): The method of claim 42 wherein the immunoactive gene product encoded by the DNA construct is a cytokine or a ligand for a natural killer cell surface receptor.

Claim 45 (withdrawn): The method of claim 42 wherein the mammal is a human.

Application No. 10/807,897 - - - - 7

Claim 46 (withdrawn): The method of claim 42 wherein the DNA construct is operably incorporated in an attenuated bacterial vector.

Claim 47 (withdrawn): The method of claim 46 wherein the attenuated bacterial vector is selected from the group consisting of attenuated *Salmonella typhimurium*, *Salmonella typhi*, *Shigella* species, *Bacillus* species, *Lactobacillus* species, *BCG*, *Escherichia coli*, *Vibrio cholerae*, *Campylobacter* species, and *Listeria* species.

Claim 48 (withdrawn): The method of claim 46 wherein the attenuated bacterial vector is an attenuated *Salmonella typhimurium*.

Claim 49 (withdrawn): The method of claim 48 wherein the attenuated *Salmonella typhimurium* is an *AroA*  $\sim$  strain of *Salmonella typhimurium*.

Claim 50 (withdrawn): The DNA vaccine of claim 49 wherein the attenuated *Salmonella typhimurium* is an *AroA*  $\sim$ , *dam*  $\sim$  strain of *Salmonella typhimurium*.

Claim 51 (new): The DNA vaccine of claim 1 wherein the DNA construct operably encoding the cancer-associated IAP-family protein comprises a polynucleotide sequence represented by SEQ ID NO: 3.

Claim 52 (new): The DNA vaccine of claim 1 wherein the DNA construct operably encoding the immunoreactive gene product comprises a polynucleotide sequence represented by SEQ ID NO: 7.

Claim 53 (new): The DNA vaccine of claim 1 wherein the DNA construct operably encoding the cancer-associated IAP-family protein comprises a polynucleotide sequence represented by SEQ ID NO: 3, and wherein the DNA construct operably encoding the immunoreactive gene product comprises a polynucleotide sequence represented by SEQ ID NO: 7.